

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 7, 2018

Ms. Leisha Abel Regulatory Coordinator Clarke Consumer Products, Inc. 675 Sidwell Court St. Charles, IL 60174

Subject: Label Amendment – Adding Optional Public Health Claims, Revising Marketing

Claims Section, Adding Optional Directions for Use, and Correcting Application Rate

Product Name: Natular DT-R EPA Registration Number: 81552-1 Application Date: January 16, 2018 Resubmission Date: May 4, 2018

Decision Number: 538379

Dear Ms. Abel:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact me by phone at (703) 308-2972, or via email at walsh.michael@epa.gov.

Sincerely,

Michael Walsh Product Manager 11 Invertebrate & Vertebrate Branch 2

Registration Division

Office of Pesticide Programs

Attachment

(text in brackets [] indicates optional text) (Alternate Brand Name: to be determined)

ACCEPTED

5/7/2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 81552-1

NATULAR® DT-R

For Outdoor [Residential] Use [Around the Home]

Active Ingredient:

Spinosad (a mixture of Spinosyn A and Spinosyn D)

Other Ingredients

Total

7.48% <u>92.52%</u> 100.00%

[Contains 0.1 gram Spinosad per [extended-release] [bi-layer] tablet. This product may absorb moisture; [therefore,] the weight of the tablet and percent by weight of active ingredient will vary with hydration.]

[U.S. Patent No. 5,362,634 and 5,496,931]

Keep Out of Reach of Children CAUTION

Precautionary Statements

Hazards to Humans and Domestic Animals

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid			
If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. 		
	 Call a poison control center or doctor for treatment advice. 		
Have the produ	ct container or label with you when calling a poison control center or doctor, or		

going for treatment. You may also contact [1-800-214-7753] [1-877-229-3763] for emergency medical treatment information.

Environmental Hazards

This product is toxic to aquatic invertebrates. Non-target aquatic invertebrates may be killed in waters where this pesticide is used.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

[Product Information]

[Through a single mosquito bite, adult mosquitoes can pose a serious threat to people and animals by transmitting [Zika,] [West Nile Virus,] [Eastern Equine Encephalitis,] [EEE,] [St. Louis Encephalitis,] [SLE,] [Dengue,] [or] [Chikungunya] [and other viruses that can cause encephalitis.]]

[Emptying or discarding small containers that are holding water will ensure the best results.] [In instances where small containers cannot be emptied or discarded and for other standing water

around the home, using NATULAR® DT-R is a simple and effective way to kill developing mosquito[es][larvae] before they become breeding and biting adults.]

[NATULAR® DT-R is a [uniquely engineered], [patented] [bi-layer] tablet for use in mosquito breeding sites. The [top][white][fizzy][effervescent] layer quickly releases a dose of active ingredient that provides rapid control of existing mosquito larvae. The [bottom][tan] layer provides a[n] [extended][slow] release of active ingredient that continually controls mosquito[es][larvae] in the water for up to [60 days][2months][5-6 weeks].] [NATULAR® DT-R's active ingredient, spinosad, is biologically derived from the fermentation of Saccharopolyspora spinosa, a naturally occurring soil organism.]

Application Directions

NATULAR® DT-R can be used in artificial containers and natural standing-water sites around your home to control the mosquito larvae of breeding mosquitoes. [NATULAR® DT-R can be applied as a preventative action (pre-flood treatment) before sites fill with water.] [NATULAR® DT-R may also be used in sites that intermittently fill with water; the NATULAR® DT-R slow release layer will stop working when dry, and begin working again when re-wetted.] NATULAR® DT-R will control mosquito larvae for up to [60 days][2months][5-6 weeks] when immersed in water. Reapply after [60 days][2months][5-6 weeks] as needed.

Restrictions

Do not apply to natural or artificial containers of water intended for consumption by people, animals, or livestock.

[In New York State, this product is only for use in containerized sites with no outflow to the natural environment.]

Application Sites [include]

[Bird Baths]

[Ornamental Fish Ponds]

[Garden Ponds]

[Containerized] [Water Gardens]

[Ornamental Fountains]

[Ornamental Pools or Ponds]

[Flower Pots or Planters]

[Rain Barrels]

. [Urns]

[Tree Holes]

[Pool Covers]

[Unused or Abandoned Swimming Pools]

[Roof Gutters]

[Roof Top Catchments]

[Storage Tanks]

[Drums]

[Buckets]

[Wheelbarrows]

[Garbage Cans]

[Other Water-Holding Receptacles]

[Floor Drains]

[Old Tires]

[Rock Holes]

[Pot Holes]

[Tire Tracks]

[Other Natural and Man-Made Depressions]

Application Rates

[1] [one] tablet treats up to 50 gallons [189 liters] for up to [60 days] [2 months] [5-6 weeks]. [For shallow [stagnant][standing] water holding areas ([<][less than][8 inches deep]), 1 [one] tablet treats up to 10 square feet of surface area.]

[For shallow [stagnant][standing] water holding areas ([<][less than][4 inches deep]), 1 [one] tablet treats up to 20 square feet of surface area.]

If gallons [liters] of water are not easy to determine, use [this] [the] table [below] [to the right] [to the left] [on the next panel] [on the front] [on the back] to determine the application rate for [1][one][each] tablet.

Application Chart			
[Average] Water Depth	Surface Area [(sq.ft.)]		
[(in.)] [(inches)]	[(ft²)]		
8	10		
4	20		
2	40		
1	80		

[For applications to contained sites smaller than a rate of [1] [one] tablet per 50 gallons, use [1] [one] tablet per contained site [(e.g., cesspools and septic tanks, transformer vaults, abandoned pools, and other small artificial water-holding containers)].]

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a cool dry place in original container only.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Warranty]

[To the extent consistent with applicable law seller makes no warranty, express or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risk of use/handling of this material when use and/or handling is contrary to label instructions.]

[For questions or comments, call [toll free] 1-800-323-5727 [or visit our website at] [insert company website]]

EPA Reg. No. 81552-1

EPA Est. No.

Produced [for] [by]
Clarke Consumer Products, Inc.
675 Sidwell Court
St. Charles, IL 60174

Net Weight:	Net Contents:	[Lot][/][Batch] Code:
[Tablet Weight:1.35g]		

[Natular® is a Registered Trademark of Clarke Mosquito Control Products, Inc.]

Optional Marketing Claims:

[For [use in] [garden ponds] [bird baths] [fish ponds] [water gardens] [rain barrels] [rainbarrels] [fountains] [ornamental pools] [roof gutters] [and] standing water]] [Controls [larvae of mosquitoes] [mosquito larvae] which may transmit [Zika,] [West Nile Virus,] [Eastern Equine Encephalitis,] [EEE,] [St. Louis Encephalitis,] [SLE,] [Dengue,] [or] [Chikungunya] [[Engineered] [Patented] [Dual Action][Bi-Layer] Tablet] [Watch It Work!] [Tablet fizzes so you know [it's] [it is] beginning to work] [Mosquito Control Tablets] [Pond][Fizzies] for mosquito larvae control] [[Pond Fizzies] [Effervescent] Mosquito Pre-treatment] [[Effervescence][Fizz][Fizzy] shows the product is beginning to work] [[Effervescence] [[Top] [White] layer] [Starts] [begins] to immediately [release active ingredient into the water] [work on killing mosquito larvae]] [No Float Design] [[Tablet][Treatment][insert product name] stays where you [put][place] it] [[Tablet][Treatment][insert product name] sinks to treat [entire] [all the] water [column]] [No [mixing] [or] [measuring] needed, simply [apply] [place] [drop] in standing water] [[720][600][360][300] Day Control with [12][10][6][5] pack] [[1][One][A] year of [control][protection] with a 6 pack] [[Controls][Kills] mosquito larvae all season long with continued use] [Kills [mosquito] larvae in treated areas] [[Mosquito] Larvae in the treated water will die] [[Tablet] [insert product name] permeates water so larvae [can't][cannot] hide] [[Each] [One] [Extended-Release] [Tablet] [Treatment] works up to 60 days] [[Effectively] [Controls][Protects] for up to [60 days][2 months][5-6 weeks]] [[60 day][2 month][5-6 week] control for your [yard][property]] [[Sustained][Extended][Continuous] release [formula]] [[Each] [One] [Bi-Layer] Tablet Kills Mosquito Larvae for up to [60 days] [2 months] [5-6 weeks]] [[Each] [One] [Bi-Layer] Tablet Provides Protection for up to [60 days] [2 months] [5-6 weeks]] [[Bottom][Tan] layer] [One treatment] Provides Protection for up to [60 days][2 months][5-6 weeks]] [[insert product name] keeps working for up to [60 days][2months][5-6 weeks]] [Kills continuously for up to [60 days][2 months][5-6 weeks]] [[Bottom layer] [One treatment] keeps killing for up to [60 days][2 months][5-6 weeks]] [[Dual action] [Bi-layer] [Tablet] fizzes for kill and then keeps working for up to [60 days][2 months][5-6 weeks]] [Easy to Use] [Easy to Apply] [Won't [Will Not] Float Away] [Effective Control] [Can be [applied to] [used in] [sites] [areas] that contain Fish and Plants] [Spinosad is biologically derived from a naturally occurring soil organism [bacterium]] [[Dual action] [Extended-Release] [Bi-layer] Tablet controls mosquito larvae] [Targets mosquito[es] [larvae]] [[Extended-Release] [Bi-layer] Tablet controls mosquito larvae, including [mosquito] species which may transmit [Zika,] [West Nile Virus,] [Eastern Equine Encephalitis,] [EEE,] [St. Louis Encephalitis,] [SLE,] [Dengue,] [or] [Chikungunya]] [Same [technology] [active ingredient] used by public health and mosquito control agencies] [[Kills][Controls] mosquito[es][larvae] in standing[stagnant] water [where adult mosquitoes breed]] [Kills mosquito[es] [larvae] before they [bite] [can become] [are] [biting] [adults]] [Preventative] [Preventative treatment for mosquito[es] [larvae]] [Prevents [future] mosquito[es][populations]] [[Effectively]Reduces mosquito populations]

[[Kills][Controls][Treats] mosquitoes at the source]

[Helps [prevent] [combats] [disease carrying] [and] [nuisance] mosquitoes from breeding]

[A [spring][pre-season][preventative] approach to [control][reduce][limit] mosquito[es] [populations]

[Mosquito Larvicide]

[An insecticide for the control of mosquito larvae]

[[Use][Apply][Treat] in early spring to prevent mosquito larvae in standing water]

[[Apply][Use in][Place in][Drop in][Treat] standing [stagnant] water [to prevent mosquitoes] [where mosquitoes breed] in or around your [house] [yard] [property]]

[[Apply][Use in][Place in][Drop in][Treat] standing [stagnant] water [to prevent mosquitoes] [where mosquitoes breed]]